

Application No.: 10/627,780

Reply to Office Action of: January 13, 2006

BASIS FOR THE AMENDMENT

Claim 1 has been amended a supported, for example, at page 21, lines 4-8 of the specification and by Claim 1 as originally filed. The remaining claims have been amended for clarity as supported by the claims as originally filed.

New Claims 8-22 have been added as supported by the specification as originally filed.

No new matter is believed to have been added by entry of this amendment. Entry and favorable reconsideration are respectfully requested.

Upon entry of this amendment Claims 1-22 will now be active in this application.

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INTERVIEW SUMMARY

Applicants wish to thank Examiner Kim for the helpful and courteous discussion with Applicants' Representative on March 2, 2006. During this discussion it was noted that none of the cited references appear to disclose the water-soluble organic solvent as claimed in step 2 of Claim 1. The Examiner agreed.

In addition, the Examiner agreed that the claims as presently amended appear to overcome the rejections as being indefinite.

REMARKS

Applicants respectfully request reconsideration of the application, as amended, in view of the following remarks.

The present invention as set forth in **amended Claim 1** relates to a method for separating nucleic acids from a sample containing nucleated cells, comprising:

- 1) bringing the sample containing nucleated cells into contact with a lysis solution containing at least a cellular component-degrading enzyme and a surfactant,
 - 2) bringing the sample containing nucleated cells into contact with a water-insoluble solid-phase carrier having an average particle size of 0.01 to 1000 μm **in the presence of a water-soluble organic solvent** to adsorb and bind nucleic acids released from the nucleated cells onto the surface of the solid-phase carrier, thereby obtaining a solid-phase carrier having adsorbed nucleic acids, and
 - 3) separating the solid-phase carrier from the sample;
- thereby separating and purifying said nucleic acids.

In contrast, WO 96/18731, Belly et al, Caldarelli-Stefano et al, Warburton et al fail to disclose or suggest bringing the sample containing nucleated cells into contact with a water-insoluble solid-phase carrier having an average particle size of 0.01 to 1000 μm **in the presence of a water-soluble organic solvent**.

As shown by a comparison of the Examples according to the present invention and Comparative Example 1, the amount of nucleic acids recovered is superior in the present invention (see Table 1 reproduced below from the specification at page 33). Comparative Example 1 uses the phenol-chloroform extraction method which takes much longer (about 3 hours) compared to the present invention.

The results of Examples and Comparative Example are shown in the following Table 1.

Table 1

	Recovered DNA concentration $\mu\text{g/ml}$	Amount of recovered DNA μg	A260/ A280	A260/ A230	DNA length	HindIII, EcoRI digestion	Globulin PCR
Example 1	168	34	1.95	2.03	150K	No trouble	No trouble
Example 2	160	32	1.98	2.01	150K	No trouble	No trouble
Example 3	185	37	2.05	2.06	150K	No trouble	No trouble
Example 4	177	35	2.04	1.99	150K	No trouble	No trouble
Example 5	184	37	1.98	1.97	150K	No trouble	No trouble
Example 6	199	40	1.99	1.99	150K	No trouble	No trouble
Example 7	184	37	2.08	2.04	150K	No trouble	No trouble
Example 8	183	365	1.97	1.98	150K	No trouble	No trouble
Comparative Example 1	120	24	1.99	2.01	150K	No trouble	No trouble

By using the method for extracting nucleic acids of the invention and the reagent thereof, nucleic acids can be purified from blood etc. in a large amount and a high purity, conveniently within a short period at a low cost. Also, the invention establishes a method that uses no toxic or corrosive solvent and thus is not harmful to working environment and workers. Therefore, the method is widely applicable to the fields of gene engineering, genetic diagnosis, genetic therapy, genome chemistry, genomic drug development, and the like. Moreover, the method is capable of automation of the treatment.

Such superior results are not disclosed or suggested by WO 96/18731, Belly et al, Caldarelli-Stefano et al, or Warburton et al alone or in combination.

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The rejection of the claims over WO 96/18731, Belly et al, Caldarelli-Stefano et al, and/or Warburton et al are believed to be unsustainable as the present invention is neither anticipated nor obvious and withdrawal of these rejections is respectfully requested.

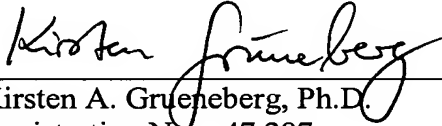
The rejection of Claims 1-6 under 35 U.S.C. § 112, 2nd paragraph, is obviated by the amendment of the claims.

This application presents allowable subject matter, and the Examiner is kindly requested to pass it to issue. Should the Examiner have any questions regarding the claims or otherwise wish to discuss this case, he is kindly invited to contact Applicants' below-signed representative, who would be happy to provide any assistance deemed necessary in speeding this application to allowance.

Respectfully submitted,

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